

**REMARKS**

The Office Action mailed March 3, 2006 has been considered in detail, and the instant amendment, Information Disclosure Statement and remarks are provided in response thereto. To begin with, the Examiner is thanked for his careful consideration of the specification and claims and in identifying various corrections that need to be made.

The status of claims 13-36 has been modified to indicate that these claims are withdrawn from further consideration as being directed to non-elected aspects or embodiments of the invention. However, upon allowance of claims 1-12 the Office is asked to reconsider rejoining withdrawn claims in view of the present examination.

A new Information Disclosure Statement (IDS) and listing of references are enclosed herein to replace the IDS originally submitted with the application. The IDS originally filed with the application was incorrect in that it did not state that this application is a continuation-in-part (CIP) claiming the benefit of the parent application under 35 U.S.C. § 120. Consequently, a copy of each reference identified in that IDS was of record in the priority application, 10/151,233, and copies did not need to be provided, 37 CFR § 1.98(d)(1). Consideration of these references by the Office is requested, and Applicant apologizes for the confusion resulting from the submission of the incorrect form.

Regarding the objections to the drawings because of a failure to refer to several of the reference characters identified by the Office, Applicant submits appropriate amendments to the specification in which each of the missing reference characters is identified. No new matter is introduced by means of these amendments, as the meaning of the reference characters is apparent from the figures themselves, and the amendments merely identify the reference characters and the

subject matter to which they refer. It is noted that the Office states that Figure 5 is said to include item 453, and that the specification makes no reference to such number. It is respectfully noted that the Office Action may have misstated the reference numeral, as 453 is identified on page 37, just above paragraph [0095]. However, it is believed that the Office Action intended to identify reference numeral 553, which is included in Figure 5. Thus, the proposed amendment to paragraph [0097] is appropriate, and withdrawal of this aspect of the objection is respectfully requested. Entry of these amendments and withdrawal of the objections are respectfully requested.

The informality in paragraph [0096] at line 19 has been corrected as suggested by the Office. The correction does not introduce new matter as the correction of the numeral is apparent from the content of the paragraph itself and corresponds to the same reference numeral at the beginning of the paragraph. Entry of the amendment and withdrawal of the objection are respectfully requested.

Claims 1, 6 and 10 are objected to based on informalities identified in paragraph 6 on page 3 of the Office Action. Each of these informalities has been corrected and introduces no new matter, as they are merely editorial in nature. The new claims are fully supported by the application as filed; in particular, the Office's attention is invited to: paragraph 52 (claim 37); paragraph 137 (claim 38); paragraphs 137 and 141 *et seq.* (claim 39); and paragraph 51 (claim 40). Entry of the amendments and withdrawal of the objections are respectfully requested.

Claims 1-3 and 6-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Hirsch et al.* ('935). *Hirsch* is said to teach an apparatus comprising the elements identified in original claim 1, including an apparatus that has a cup having an interior and first and second openings as well as an

electrode disposed within the interior. *Hirsch* is said also to teach a source of suction that is connected to one of the openings so that when the first opening is placed over a region of tissue and suction is applied to the second opening, an electrical connection is made between the region of tissue to be examined and the electrode. Furthermore, it is said that a flange surrounds the first opening and that the source of suction can be a syringe or an aspirator. Furthermore, the Office states that *Hirsch* also discloses a measuring device in communication with the electrode to determine an electrical signal from the electrode and that a display device may display the electrical signal from the electrode. This rejection is traversed.

While the Office has described various salient features of *Hirsch* that are generally relevant to the instant invention, the specific features of *Hirsch* differ from the present invention and are clearly distinguished by the instantly amended claims. In particular, *Hirsch* describes an apparatus that is specifically designed to allow the internal electrode to make contact with the patient's skin when the apparatus is placed at the skin surface. (col. 2, lns. 48-51) To accomplish this, *Hirsch* describes a device wherein the cup housing is made of a resilient, deformable material so that when suction is applied, the wall of the cup deforms, allowing the internal electrode to be drawn down onto the patient's skin to make the required contact. (col. 2, lns. 29-59 and claim 1) In contrast, the apparatus and methods of the instant invention are directed not to the surface of the skin but to determining the transepithelial electropotential and/or impedance characteristics in order to diagnose pre-malignancy or cancer. The instant apparatus is also designed to allow for the introduction of various pharmacological agents in order to challenge the transepithelial tissue and thereby further

characterize its condition. Instantly amended claim 1 specifically identifies features of the apparatus that are consistent with determining the condition of an epithelial region of tissue, thereby distinguishing the present invention from *Hirsch*. As further evidence that the *Hirsch* apparatus does not anticipate the present claims, it is respectfully suggested that the apparatus of *Hirsch* is incapable of being used to obtain epithelial electrical measurements as with the apparatus of the instantly claimed invention. In other words, an apparatus wherein an electrode makes contact with the surface of the skin as described in *Hirsch* cannot be used for determining the transepithelial condition of tissue. Furthermore, *Hirsch* is merely directed to the use of an electrode for the purposes of sensing a voltage or current after the electrode makes contact with the surface of the skin. In contrast, the apparatus of the present invention is directed to a current-passing electrode disposed within the interior of the cup, as set forth in amended claim 1. Consequently, the apparatus of the instant claim is structurally distinguished from the apparatus of *Hirsch*. It is also observed that the apparatus of *Hirsch* utilizes suction as applied to a resilient cup material in order to draw down the electrode and have it make contact with the surface of the skin. In contrast, as described throughout the present application, suction is utilized as a means of opening ductile passages in order that the electrical measurements can be directly made of the epithelial region of tissue. See, for example, paragraphs [0098] and [0140]. This feature is now emphasized by the amendment to claim 1 wherein it is stated, "an electrical connection is made between the epithelial region of tissue to be examined and the electrode." Withdrawal of this aspect of the rejection is respectfully requested.

Claims 4 and 5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hirsch* in view of *Lundbäck* ('404).

The Office explains that *Hirsch*, as described in the previous paragraph, teaches all of the limitations of the claims except that an electroconductive medium is provided to facilitate an electrical connection between the region of tissue to be examined and the electrode. It is argued that *Lundbäck* teaches that it is known to apply electroconductive agents, such as conductive gel or physiological saline, to tissue in order to improve electrical contact between the skin and a biomedical electrode element. (col. 1, lns. 29-35) It is concluded that it would have been obvious to one having ordinary skill in the art to utilize an electroconductive medium such as a saline solution with an electrode apparatus similar to that of *Hirsch* in order to improve electrical contact between the skin and the electrical element. This rejection is traversed.

As noted above, *Hirsch* provides an inadequate basis for rejection of claim 1, and therefore claims 4 and 5 dependent on claim 1 should be allowable on this basis alone. However, it is further noted that *Lundbäck* relates to the use of saline or a conductive gel merely to improve electrical contact between the surface of the skin and an electrical sensing electrode. As discussed above, the present invention is directed to a current-passing electrode rather than merely an electrical sensing electrode. Furthermore, the agents utilized in the present invention are applied so as to infuse or diffuse into a duct and thereby either improve the electrical measurement of a subsurface epithelial feature or modify the response of the body to the agent used. This aspect of the invention is significantly different from both *Hirsch* and *Lundbäck*, which are both directed to mere surface skin measurements. In summary, *Lundbäck* cannot cure the underlying deficiencies in *Hirsch* and is merely directed to an incidental feature of improving contact with the skin surface and does not suggest any possibility of affording an improvement to the passage of an electrical current

into a duct or beneath the surface of the skin or measuring an electrical property of a tissue region beneath the surface of the skin, such as an epithelial region. Withdrawal of this rejection is respectfully requested.

Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hirsch* in view of *Dempsey et al.* ('222). The Office states that *Hirsch* teaches all of the limitations of the claims except for the use of wireless connections between the measuring unit and the electrode and between the measuring device and the display device. *Dempsey* is said to cure those deficiencies, thereby rendering claims 11 and 12 obvious. It is respectfully noted that in view of the underlying deficiencies of *Hirsch* with regard to the present claims, which *Dempsey* does not cure, therefore claims 11 and 12 are similarly allowable in view of the underlying patentability of claim 1. Withdrawal of this aspect of the rejection is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

Application No.: 10/717,074

Docket No.: DAVIES 3.0-001 CIP I

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: September 1, 2006

Respectfully submitted,

By 

Harvey L. Cohen

Registration No.: 28,365

LERNER, DAVID, LITTENBERG,

KRUMHOLZ & MENTLIK, LLP

600 South Avenue West

Westfield, New Jersey 07090

(908) 654-5000

Attorney for Applicant

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